

PATENT APPLICATION

Attorney Docket No. C04036US (98029.4C)

TITLE OF THE INVENTION:

METHOD OF MANUFACTURING A SOFT HEARING AID

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SPECIFICATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of co-pending U.S. Patent Application Serial
No. 09/855,095, filed 14 May 2001 (now U.S. Patent No. 6,695,943), which is a
continuation-in-part of co-pending U.S. Patent Application Serial No. 09/311,156, filed 13
May 1999 (now U.S. Patent No. 6,354,990), which is a continuation-in-part of co-pending
U.S. Patent Application Serial Nos. 09/181,539, 09/181,540 (now U.S. Patent No.
6,432,247), 09/181,541 (now U.S. Patent No. 6,438,244), 09/181,842 (now U.S. Patent No.
6,254,526), 09/181,843 (now U.S. Patent No. 6,434,248), 09/181,844 (now U.S. Patent No.
6,228,020) and 09/181,845 (now U.S. Patent No. 6,473,512), all filed 28 October 1998,
which are continuations-in-part of U.S. Patent Application Serial No. 09/084,864, filed 26
May 1998 (now U.S. Patent No. 6,022,311). Each of these patent applications and patents are
incorporated herein by reference. Priority of each of these patent applications is hereby
claimed.

This is also a continuation-in-part of co-pending U.S. Patent Application Serial No.
10/097,540, filed 11 March 2002, which is a divisional of U.S. Patent Application Serial No.
09/311,156.

Priority of U.S. Provisional Patent Application Serial No. 60/456,057, filed 20 March 2003, incorporated herein by reference, is hereby claimed.

Priority of U.S. Provisional Patent Application Serial No. 60/450,898, filed 28 February 2003, incorporated herein by reference, is hereby claimed.

5 Priority of U.S. Provisional Patent Application Serial No. 60/203,983, filed 12 May 2000, incorporated herein by reference, is hereby claimed.

Priority of U.S. Provisional Patent Application Serial No. 60/068,036, filed 18 December 1997, incorporated herein by reference, is hereby claimed.

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

10 Not applicable

REFERENCE TO A "MICROFICHE APPENDIX"

Not applicable

BACKGROUND OF THE INVENTION

1. Field of the Invention

15 The present invention relates to hearing aids and more particularly to an improved hearing aid and its method of manufacture. More particularly, the present invention provides an improved method for constructing a hearing aid combining a mounting member (for example, a receptacle or face plate) with a soft polymeric body that is joined to the mounting member and which encapsulates one or more of the electronic hearing aid components of the apparatus, the
20 soft polymeric body being sized and shaped to conform to the user's ear canal during use. In one form, a soft polymeric material is used as the face plate.

2. General Background of the Invention

The hearing industry has realized major strides in the development of high-fidelity, high-performance products, the most recent of which is digital signal processing technology. Hearing
25 care professionals expected those advancements to solve the shortcomings of traditional amplification, and to push the market forward. Those expectations have not been fully realized. While these developments have solved many of the problems associated with traditional electronic design and steadily gained market share, they have not fostered overall market growth.

30 The issues of early acoustic feedback, less than optimum fidelity and intermodulation of the frequency response cannot be completely resolved by electronic manipulation of the signal by either analog or digital means.

Historically, custom-molded ear worn hearing instruments have been limited to an "acrylic pour" process as the means of the construction. With the advent of miniaturization and technological advancement of computer chip programming, the ear-worn instruments have become smaller and are positioned into the bony portion of the ear canal, commonly referred to as "deep insertion technology."

Developments outside the hearing industry have culminated in a new level of micro-miniaturization of electronic components for industry applications. Consequently, advanced signal processing can be housed in less space than was required for traditional electro-acoustic components.

With the development of programmable hearing aids, using either analog or digital signal processing, custom electronic design has shifted from the manufacturing level to the clinical level. The clinician can now customize the electro-acoustic response via software. It is no longer necessary for the device to be returned to the manufacturer for hardware changes to arrive at the desired electro-acoustic response. However, it is still often necessary to return the device for shell modifications.

In direct contrast to electronic advances within the industry, little or no advancement has been realized in custom prosthetic design. Since the late 1960's, when the custom in-the-ear hearing aid was developed, materials and construction techniques remained virtually unchanged. These materials and techniques were adopted from the dental industry, whereby the customized housing-commonly called a "shell" was constructed using acrylic of 90 point Durometer Hardness Shore D. This construction process provided the structure and the strength of material necessary to protect the electronics.

At the time the acrylic shell was developed, hearing instruments were worn in the relatively forgiving cartilaginous portion of the ear canal. Micro-miniaturization of electronic components, combined with increased consumer demand for a cosmetically acceptable device, has shifted the placement of the hearing aid toward the bony portion of the ear canal.

The bony portion of the canal is extremely sensitive and intolerant of an acrylic shell when that shell is over sized due to standard waxing procedures or is in contact with the canal wall beyond the second anatomical bend. Rigid acrylic that does not compress must pivot in reaction to jaw or head movement, thereby changing the direction of the receiver yielding a distorted acoustic response. In addition, the pivot action causes displacement of the device

resulting in unwanted acoustic feedback. This problem has necessitated countless shell modifications, thereby compromising the precision approach of the original dental technology. Many such devices require some modification by the manufacturer. Most manufacturers can expect a high percentage of returns for modification or repair within the first year. Consequently, 5 CIC (completely in canal) shell design has been reduced to more of a craft than a science. Although the recent introduction of the ultra-violet curing process has produced a stronger, thinner shell, the overall Shore Hardness remained unchanged.

The current trend for custom hearing aid placement is to position the instrument toward the bony portion of the ear canal. The ear canal can be defined as the area extending from the 10 concha to the tympanic membrane. It is important to note that the structure of this canal consists of elastic cartilage laterally, and porous bone medially. The cartilaginous portion constitutes the outer one third of the ear canal. The medial two-thirds of the ear canal is osseous or bony. The skin of the osseous canal, measuring only about 0.2 mm in thickness, is much thinner than that of the cartilaginous canal, which is 0.5 to 1 mm in thickness. The difference in thickness directly 15 corresponds to the presence of apocrine (ceruminous) and sebaceous glands found only in the fibrocartilaginous area of the canal. Thus, this thin-skinned thinly-lined area of the bony canal is extremely sensitive to any hard foreign body, such as an acrylic hearing instrument.

Exacerbating the issue of placement of a hard foreign body into the osseous area of the ear canal is the ear canal's dynamic nature. It is geometrically altered by temporomandibular 20 joint action and by changes in head position. This causes elliptical elongation (widening) of the ear canal. These alterations in canal shape vary widely from person to person. Canal motion makes it very difficult to achieve a comfortable, true acoustic seal with hard acrylic material. When the instrument is displaced by mandibular motion, a leakage or "slit leak" creates an open loop between the receiver and the microphone and relates directly to an electroacoustic distortion 25 commonly known as feedback. Peripheral acoustic leakage is a complex resonator made up of many transient resonant cavities. These cavities are transient because they change with jaw motion as a function of time, resulting in impedance changes in the ear canal. These transients compromise the electroacoustic performance.

The properties of hard acrylic have limitations that require modification to the hard shell 30 exterior to accommodate anatomical variants and the dynamic nature of the ear canal. The shell must be buffed and polished until comfort is acceptable. The peripheral acoustic leakage caused

by these modifications results in acoustic feedback before sufficient amplification can be attained.

Hollow shells used in today's hearing aid designs create internal or mechanical feedback pathways unique to each device. The resulting feedback requires electronic modifications to "tweak" the product to a compromised performance or a "pseudo-perfection". With the industry's efforts to facilitate the fine-tuning of hearing instruments for desired acoustic performance, programmable devices were developed. The intent was to reduce the degree of compromise, but by their improved frequency spectrum the incidence of feedback was heightened. As a result, the industry still falls well short of an audiological optimum.

A few manufacturers have attempted all-soft, hollow shells as alternatives to acrylic, hollow shells. Unfortunately, soft vinyl materials shrink, discolor, and harden after a relatively short period of wear. Polyurethane has proven to provide a better acoustic seal than polyvinyl, but has an even shorter wear life (approximately three months). Silicones have a long wear life but are difficult to bond with plastics such as acrylic, a necessary process for the construction of custom hearing instruments. To date, acrylic has proven to be the only material with long term structural integrity. The fact remains, however, that the entire ear is a dynamic acoustic environment and is ill-served by a rigid material such as acrylic. Also, the acrylic hearing aids typically need to be returned to the manufacturer for major shell modifications.

The following references are all incorporated herein by reference:

U.S. Patent Nos.: 4,051,330; 4,375,016; 4,607,720; 4,716,985; 4,811,402; 4,870,688; 4,880,076; 4,937,876; 5,002,151; 5,068,902; 5,185,802; 5,201,007; 5,259,032; 5,530,763; 5,430,801; 5,500,902; and 5,659,621.

A Japanese reference that discusses a hearing aid that features a thin wall soft shell is the Takanishi patent application number 1989-238198.

Also of interest and incorporated herein by reference are published Japanese patent application no. JA61-238198, the articles from December 1997 Journal of American Academy of Audiology, and Staab, Wayne J. and Barry Finlay, "A fitting rationale for deep fitting canal hearing instruments", Hearing Instruments, Vol. 42, No. 1, 1991, pp. 7-10, 48.

BRIEF SUMMARY OF THE INVENTION

The present invention provides a method and material for the construction of a soft hearing instrument that is solid (i.e. eliminates void spaces). This instrument includes a soft body

portion that is truly soft, comprising an elastomer of about 3 to 55 durometer Shore A and preferably 10-35 durometer Shore A. This product is unique in that it is solid, with the electronic components actually encapsulated or embedded within the soft fill material. The fill material can be a Dow Corning® MDX-4-4210 silicone or a silicone polymer distributed by
5 Factor II, Inc. of Lakeside, Arizona, designated as product name 588A, 588B, 588V.

The present invention provides a method that can replace traditional acrylic shell construction. Unlike the shell construction process, the ear impression is not modified, built up, or waxed. With the elimination of these steps, a more faithful reproduction of the ear impression is accomplished. With the present invention, the manufacturer should be able to produce a
10 hearing aid body which will not need to be returned as frequently for modification as with present hard acrylic hearing aid bodies.

The apparatus of the present invention is virtually impervious to the discoloration, cracking, and hardening experienced with polyvinyls and polyurethanes.

The hearing aid of the present invention provides a greater range of gain before feedback
15 occurs.

The outer surface of the body of the present invention is preferably non-absorbent and virtually impervious to cerumen.

As used herein, "in the ear hearing aids" includes all hearing aids which have all of the electronics positioned in the ear, and thus includes hearing aid styles ranging from full concha
20 to CIC (completely in the canal) hearing aid styles. An embodiment of the present invention shown in the drawings is a CIC hearing aid style.

BRIEF DESCRIPTION OF THE DRAWINGS

For a further understanding of the nature, objects, and advantages of the present invention, reference should be had to the following detailed description, read in conjunction with
25 the following drawings, wherein like reference numerals denote like elements and wherein:

Figure 1 is a sectional elevational view of a user's hearing area to show the anatomy thereof;

Figure 2 is a sectional elevational view of a user's ear canal showing placement of a dam
30 and mold material as part of the method of the present invention;

Figure 3 is a perspective view of the form portion used with an embodiment of the

method of the present invention;

Figure 4 is a perspective view illustrating shaping of the form as part of the method of the present invention;

5 Figure 5 is a perspective view illustrating a dipping of the form into a vessel carrying material for making the female mold as part of the method of the present invention;

Figure 6 is a perspective view illustrating a coating of the form with the female mold as part of the method of the present invention;

10 Figure 7 is a partial elevational view of an embodiment of the apparatus of the present invention illustrating the mounting member and the plurality of the electronic hearing aid components;

Figure 7A is a cross-sectional view taken along the line 7A-7A in Figure 7;

Figure 7B is a partial view showing the portion indicated in Figure 7 as 7B;

Figure 8 is a elevational view of the lateral side of the mounting member taken along lines 8-8 of Figure 7;

15 Figure 9 is a perspective view illustrating the method step of joining the female mold to the mounting member at the medial side thereof;

Figure 10 is a perspective view of an embodiment of the apparatus of the present invention and showing the method of the present invention after the joining of the female mold and mounting member;

20 Figure 11 is a perspective view illustrating the method step of adding filler material to the interior of the female mold and encapsulating electronic hearing aid component portions of the apparatus;

Figure 12 is a perspective view illustrating removal of the female mold after the filler material has set and encapsulating the electronic hearing aid components;

25 Figure 13 is a perspective of an embodiment of the apparatus of the present invention and the method of the present invention illustrating removal of excess plate and tube material from the mounting member;

Figure 14 is a perspective view of an embodiment of the apparatus of the present invention;

30 Figure 15 is an elevational view of an embodiment of the apparatus of the present invention;

Figure 16 is an end view of an embodiment of the apparatus of the present invention taken along lines 16-16 of Figure 15;

Figure 17 is a top view of an embodiment of the apparatus of the present invention taken along lines 17-17 of Figure 15;

5 Figure 18 is a graphical representation of a comparison of real ear occlusion gain for the present invention versus a hard shell, hollow-type instrument;

Figure 19 is a graphical representation showing a comparison of real ear aided gain obtained before acoustic feedback, comparing the present invention with a hard shell, hollow-type instrument;

10 Figure 20 is a perspective view illustrating an alternate method of the present invention, namely the initial step of forming the female mold;

Figures 21-22 show the alternate method of the present invention including a heating of the vacuum forming film material;

15 Figure 23 is a perspective view of the alternate method of the present invention shown during vacuum forming;

Figure 24 is a perspective view of the alternate method of the present invention showing the female mold as part of a vacuum formed sheet;

Figure 25 is a perspective view of the alternate method of the present invention showing removal of the female mold from the vacuum molded sheet;

20 Figure 26 is a perspective view of the method of the present invention showing the female mold after forming using the method steps of Figures 23-25;

Figure 27 is a partial perspective view showing a second alternate embodiment of the method of the present invention, showing the coating of the vent tube;

25 Figure 28 is a partial perspective view showing a second alternate embodiment of the method of the present invention, showing removal of the mold to provide a soft solid body with contained vent tube and insert;

Figure 29 is a partial perspective view showing a second alternate embodiment of the method of the present invention, illustrating an insertion of the hearing aid component assembly into the void space that was formed by removal of the insert;

30 Figure 30 is a perspective view that illustrates the second alternate embodiment of the method and apparatus of the present invention;

Figure 31 is a perspective view illustrating the second alternate embodiment of the method and apparatus of the present invention; and

Figure 32 is a perspective view illustrating the second alternate embodiment of the method and apparatus of the present invention.

5 DETAILED DESCRIPTION OF THE INVENTION

Figures 1 and 2 show a user's ear 1 and anatomical parts of the ear. In Figure 1 there can be seen the external auditory canal 2, ear canal wall 3, auricle 4, isthmus 5, tympanic membrane 6, middle ear 7 and inner ear 8. In Figure 2 a dam 9 such as a cotton dam or otoblock dam is positioned at the isthmus 5. The dam 9 is used as a first step of an embodiment of the method of the present invention wherein a form portion 11 or impression material is formed of silicone, methylmethacrylate or alginate. The form 11 is formed in between dam 9 and auricle 4 as shown in Figure 2.

During the method step of making form 11, the form 11 conforms to all of the curvatures of the ear canal 3 so that an accurate form 11 is provided for making a female mold.

15 The female mold 15 is shown in Figures 6 and 9-12. In Figures 3 and 4, the form 11 is shown after being removed from the ear 1 (Figure 3) and during a cutting of the form 11 using knives 12 to cut excess material that is designated as 13, 14 in Figure 4. The form 11 is separated from excess material 13 and 14 at sagittal plane 16. After the form 11 is trimmed in Figure 4, a technician's hand 18 dips the form 11 into vessel 17 as schematically indicated by the arrow 20. 20 The vessel 17 includes a liquid material 21 that cures at room temperature, such as room temperature curing methacrylate (sold by Esschem). A clear material 21 can be used in the method step shown in Figure 5.

In Figure 6, the technician's hand 18 has removed the form 11 so that a coating of material 21 cures at room temperature (or with an ultraviolet light process) to form female mold 15 on form 11. After it cures, the female mold 15 is removed from form 11 for use as shown in Figures 9 and 10 during assembly of the apparatus 10 of the present invention. The mold 15 can be a few millimeters in wall thickness (typically 1-3 mm).

25 A number of electronic components are mounted to a mounting member 22 prior to use of the female mold 15. Mounting member 22 provides a medial side 23 and lateral side 24. The medial side 23 supports a number of hearing aid electronic components as shown in Figures 7, 9, and 10. In Figure 7, these hearing aid electronic components include commercially available 30

hearing aid components including a microphone 25, volume control, battery, socket or plug 28 for communicating with a computer, chip or micro processor circuit, wiring harness 38, input capacitor, amplifier 34, receiver/speaker 35, and receiver tube 37.

In Figure 8, the lateral side 24 of mounting member 22 shows the microphone 25, battery compartment 26, volume control 27, programming socket 28 for communicating with a computer, silicone plug 54 (see Figure 9), and vent opening 29 that communicates with vent tube 30 (see Figure 10). In Figure 9, battery 31 is shown housed in battery compartment 26. The electronic hearing aid components also include a battery terminal 32, voltage regulating capacitor 33 (see Figure 15), amplifier/microprocessor 34, receiver 35 having speaker port 36, and receiver tube 37. A wiring harness 38 includes a plurality of wires that connect to various electronic components of the hearing aid device together. The wiring harness 38 includes a length of wires 39 that are arranged in an S or multiple curved pattern as shown in Figure 7. This "S loop" configuration of wires 39 helps protect the integrity of the electronics when the hearing aid apparatus 10 is flexed as occurs during use because of its soft nature. Further, the S-loop wires 39 are preferably a 44 gauge five strand Litz wire (or magnet wire). The length of the S-loop wires 39 is preferably at least 1.5 times the distance between the terminals to the receiver (or microprocessor) 35 and the amplifier 34 terminals. These "S-Loop" wires 39 prevent excess tension or compression from being transmitted to the electronics during use (e.g. flexing, elongation, compression of hearing aid 10).

Vent tube 30 is anchored to the mounting member 22 and preferably also to one of the electronic components at a position spaced away from the mounting member 22. Vent tube 30 acts as a tensile load carrying member that carries tension so that the wiring harness 38 is substantially free of a tensile load that could damage the wiring harness 38. Also, when vent tube 30 is anchored to one of the electronic components (such as receiver 35) at a position spaced away from the mounting member 22, it may provide enough strain relief that it would not be necessary to coil wires 39 as shown (they could be straight instead).

Something else could be used as a load carrying member, in place of vent tube 30 (in which case vent tube 30 would not necessarily be anchored to one of the electronic components (such as receiver 35)) at a position spaced away from the mounting member 22. For example, a monofilament cantilever 55 can be used to carry tension so that tension is not transmitted to wiring harness 38. In Figures 7, 7A, and 7B the link 55 is anchored to plate 22 at opening 56.

Fastener 57 affixes to receiver tube 37 at large opening 59. Monofilament cantilever 55 attaches to fastener 57 at smaller diameter opening 58. Alternatively, vent tube 30 could be manufactured of a tensile material that carries tensile load. The vent tube 30 would then be anchored to plate 22 and fastener 57 as the tensile member.

5 The monofilament cantilever 55 provides longitudinal stability to the body. It minimizes longitudinal displacement (stretching as well as compression) and thus acts as a longitudinal stabilizer (a longitudinal load carrying member). As described above the monofilament cantilever 55 can be used as an alternative embodiment.

10 After the electronic components (sometimes designated generally in the drawings by the letter "E") are assembled to the medial 23 side of mounting member 22, female mold 15 is used to complete the method of construction of the present invention as shown in Figure 9-13. In Figure 9, the female mold 15 is placed over the electronic components "E" beginning with the distal end portion of receiver tube 37 and the distal end portion of vent tube 30 as indicated by arrows 40 in Figure 9. A plurality of three openings 41, 42, 43 are provided at distal end 44 of female mold 15 as shown in Figure 9. The proximal end 45 of female mold 15 provides an annular edge surface 19 that engages the medial 23 side of mounting member 22 as indicated by the dotted line 46 in Figure 9.

15 A joint is formed between annular edge surface 19 of female mold 15 and medial surface 23 of mounting member 22 at a position schematically indicated as dotted line 46 in Figure 9, using the method of the present invention. The medial surface 23 of mounting member 22 is cleaned with a suitable solvent. Acetone can be used as a solvent in the case of a mounting plate 22 that is made of acrylic. The medial surface 23 of mounting member 22 is then painted with a primer using a swab or brush. The primer is allowed to dry. A bonding agent is then applied to the medial surface 23 of mounting member 22 and allowed to dry. The bonding agent or bonding enhancer can be product A-320 of Factor II, Inc. of Lakeside, Arizona, which is a member of the chemical family "silicone primer".

20 The female mold 15 is placed against the medial side 23 of mounting member 22. A liquid acrylic is used to form an acrylic seam at the interface of annular edge surface 19 of female mold 15 and the medial side 23 of mounting member 22 (see Figure 10). As the female mold 15 is assembled to mounting member 22, vent tube 30 passes through opening 41. Receiver tube 37 passes through opening 42. The opening 43 is then used for injection of filler material 50 (e.g.

via needle 49) as shown by arrows 51, 52 in Figure 11. During this process, temporary seal 47 holds the liquid filler material 50 within the interior 53 that is formed by female mold 15 and mounting member 22. The filler material 50 can be a liquid during the injection step of Figure 11 so that it encapsulates at least the receiver/speaker electronic component 35 and preferably other components as well.

In Figure 12, the female mold 15 is removed after the material 50 has set. The mounting member 22 (which can be in the form of a circular, generally flat face plate) is then cut at the phantom line 46 that basically tracks the periphery of female mold 15 at annular edge surface 19 at proximal end 45 thereof. This cutting of the unused, unneeded part of mounting member 22 is shown in Figure 13. Figures 14-17 show the completed apparatus 10 of the present invention.

The present invention provides a soft, yet solid hearing aid instrument that will provide a more appropriate environment for both the high fidelity performance of today's advanced circuitry and the dynamic ear canal.

The present invention teaches a soft construction of at least the distal portion of the apparatus 10 so that at least the receiver/speaker is encapsulated with the soft material 50. This construction results in a precise representation of the human ear canal, flex with jaw motion, and cushion for the embedded electronic components "E".

Figure 18 demonstrates real ear occlusion gain (REOG) finding obtained from a wearer having a tortuous ear canal. The curve 101 represents the REOG of a hard shell, hollow type hearing aid instrument. The curve 102 represents the REOG of an instrument 10 made according to the method of the present invention. As can be seen in Figure 18, the present invention instrument provided 20 dB more attenuation than did the hard shell, hollow hearing aid instrument represented by the curve 101. Because of the sharp first directional bend of the wearer's ear canal, the hard shell instrument could not be inserted without modification. The apparatus 10 of the present invention was insertable without modification thereby yielding a tighter seal in the wearer's ear.

Figure 19 is a graphical representation that demonstrates real ear aided gain (REAG) findings obtained from a wearer having a tortuous ear canal. The curves shown (103, 104) were obtained from the instruments used to generate the finding shown in Figure 18. Curve 103 represent REAG before feedback of the apparatus 10 of the present invention. Curve 104 demonstrates the REAG before feedback of a hard shell, hollow type hearing aid instrument of

the prior art. As can be seen in Figure 19, the instrument 10 of the present invention represented by curve 103 provided more gain across the frequencies. This REAG is inversely proportional to the amount of occlusion gain (REOG) or attenuation provided by the apparatus 10 of the present invention. It should be restated that, because of the sharp first directional bend of the wearer's ear canal, the hard shell, hollow type instrument of the prior art could not be inserted without being modified. The apparatus 10 of the present invention was insertable without modification, thus the present invention provides higher added gain values (REAG) when a more negative REOG can be achieved while maintaining comfort.

Figures 20-25 show an alternate method for forming the female mold that is then used with the embodiment of Figures 1-19. The female mold is designated generally by the numeral 15A in Figure 26 after forming and using the method steps shown in Figures 20-25. In Figure 20, a vacuum mold apparatus 60 has a base 61 that supports a post 62 and heating element 63. Base 61 contains a vacuum pump. Frame 64 can be pivotally mounted to base 61 at post 62. Frame 64 provides opening 65.

A matrix 66 of small openings is provided at the upper portion of base 61. Matrix 66 of openings communicates with the vacuum pump in base 61. In Figure 21, the sheet of film material 67 is placed into and raised with frame 64 as indicated by arrows 68 in Figure 21. In Figure 22, the sheet of film material 67 is heated by heating element 63 as frame 64 engages or is positioned closely to the heating element 63. Arrows 69 indicate that frame 64 is lowered after heating element 63 heats sheet of film material 67 (Figures 22). Male mold 70 is placed upon matrix 66 so that when the heated and softened sheet of film material 67 is lowered with frame 64, the sheet of film material 67 deforms and conforms to the male mold 70 as shown in Figures 23 and 24.

A vacuum is drawn through the matrix of opening 66 using the vacuum pump in base 61 as indicated by the arrows 71 in Figure 23. When the vacuum is discontinued, the male mold 70 is withdrawn, and the female mold 15A is formed as part of sheet 67 as shown in Figures 24 and 25. The female mold 15A can then be removed using knife 72. Figure 26 shows the completed female mold 15A.

It should be understood that the female mold 15A can be used in place of the female mold 15 in the embodiment of Figures 1-19 and in the method of Figures 1-19.

Figures 27-32 show a second alternate embodiment of the apparatus of the present

invention, and illustrate the second alternate embodiment of the method of the present invention. In Figures 27-32, a second, alternate embodiment of the apparatus of the present invention is shown, designated generally by the numeral 75 in Figures 29, 30 and 31. Hearing aid 75 is constructed using the method shown in Figures 27-32. In Figure 27, vent tube 76 is shown prior to attachment to mounting member (e.g. acrylic) 77. The mounting member 77 has an opening 78. It should be understood that the mounting member 77 can receive any of the female molds 15, 15A shown in the embodiments of Figures 1-26.

An insert 79 includes several sections designed to simulate portions of a hearing aid component assembly 105. For example, the insert 79 can include a section 80 designed to simulate an electronic hearing aid component, namely a receiver. The insert section 81 is designed to simulate a wiring harness. The insert section 82 is designed to simulate a battery compartment or battery receptacle.

Once the selected mold such as 15, 15A is attached to mounting member 77, it can be filled with a polymeric material (preferably silicone), such as is shown in Figure 11. However, in the embodiment of Figures 27-32, vent tube 76 is first coated with a bonding agent 149 such as A330 available from Factor II of Lakeside, Arizona. The vent tube 76 is then placed inside the mold cavity 15, 15A. The mold 15, 15A is then attached (bonded) to mounting member 77 as shown and described with respect to the embodiments of Figures 1-26 (see Figure 11). Once the polymeric material has cured inside mold cavity, the mold 15, 15A can be removed as indicated schematically by arrow 94. A technician then removes insert 78 as indicated schematically by the arrow 83 in Figure 28. The insert 79 includes an insert section 80 that simulates a receiver, an insert section 81 that simulates a wiring harness and an insert section 82 that simulates a battery compartment or battery receptacle. However, other shapes can be used for insert 136 so that a cavity 141 of desired shape is achieved. Upon removal of the insert 79, a cavity 84 is left behind, the cavity 84 being positioned next to vent tube 76 as shown in Figure 28.

The cavity 84 simulates the sections of the provided insert 79, including a cavity section 85 that simulates a receiver, a cavity section 86 that simulates a wiring harness and a cavity section 87 that simulates a battery case or receptacle.

The bonding enhancer 92 can be applied to vent tube 76 using a spray or brush 88 as shown in Figure 27 as indicated schematically by the arrow 89. Vent tube 76 thus has an outer surface 90 that becomes coated with the bonding enhancer or bonding agent 92. Vent tube 76

provides a bore 91 which is not coated with the bonding enhancer, as it remains open to vent air flow in between the patient's ear canal and the exterior of the ear canal and hearing aid 75.

The polymeric filler material 93 that is added to mold 15, 15A cavity forms a soft and solid body having the provided cavity 84 into which a hearing aid component assembly 105 can be inserted, as indicated schematically by arrows 99 in Figure 29. This hearing aid component assembly can include both electronic hearing aid components and other components. As an example, in Figure 29, the hearing aid component assembly 105 includes a receiver 95, receiver tube 96, wiring harness 97, and a battery compartment 98 that includes other hearing aid components such as battery 101, a microphone, an amplifier, or other desired hearing aid components.

Figures 29-31 illustrate the completion of and insertion of hearing aid component assembly 105 into the cavity 84 that was formed after the polymeric filler material 93 had cured and set, and after which the shaped insert 79 had been removed. In Figure 31, arrows 100 schematically indicate a severing of excess vent tube 76 material and the severance of excess material from receiver tube 96. The receiver tube 96 and vent tube 76 communicate with the patient's inner ear generally opposite mounting member 77 as shown in Figures 28-31. The vent tube 76 also communicates with the exterior of the patient's ear via an opening 104 in mounting member 77 (see figure 32). A connection 103 can be formed between vent tube 76 and mounting member 77 using a needle 102 to apply an adhesive or other connection material or structure, for example.

The apparatus 10 of the present invention will result in a better utilization of advanced circuitry and a more comfortable hearing instrument. The soft construction solves the problem of peripheral leakage, poor fit, and pivotal displacement that often occurs with jaw motion.

Another problem that is solved with the present invention is the elimination of internal cross-talk of components housed in hollow shell type hearing aids.

The following table lists the parts numbers and parts descriptions as used herein and in the drawings attached hereto.

PARTS LIST

Part Number	Description
1	ear
2	external auditory canal

	3	ear canal wall
	4	auricle
	5	isthmus
	6	tympanic membrane
5	7	middle ear
	8	inner ear
	9	dam
	10	hearing aid
	11	form
10	12	knife
	13	excess material
	14	excess material
	15	female mold
	15A	female mold
15	16	sagittal plane
	17	vessel
	18	technician's fingers
	19	annular surface
	20	arrow
20	21	mold material
	22	mounting member
	23	medial side
	24	lateral side
	25	microphone
25	26	battery compartment
	27	volume control
	28	programming socket
	29	vent opening
	30	vent tube
30	31	battery
	32	battery terminal

	33	voltage regulating capacitor
	34	amplifier/microprocessor
	35	receiver
	36	receiver port
5	37	receiver tube
	38	wiring harness
	39	s-loop wires
	40	arrow
	41	opening
10	42	opening
	43	opening
	44	distal end
	45	proximal end
	46	dotted line
15	47	temporary seal
	48	syringe
	49	needle
	50	filler material
	51	arrow
20	52	arrow
	53	interior space
	54	silicone plug
	55	monofilament cantilever
	56	opening
25	57	fastener
	58	small opening
	59	large opening
	60	vacuum mold
	61	base
30	62	post
	63	heating element

	64	frame
	65	opening
	66	matrix
	67	sheet of film material
5	68	arrow
	69	arrow
	70	male mold
	71	arrow
	72	knife
10	75	hearing aid
	76	vent tube
	77	mounting member
	78	opening
	79	insert
15	80	insert section
	81	insert section
	82	insert section
	83	arrow
	84	cavity
20	85	cavity section
	86	cavity section
	87	cavity section
	88	brush
	89	arrow
25	90	outer surface
	91	bore
	92	bonding agent
	93	filler material
	94	arrow
30	95	receiver
	96	receiver tube

5	97	wiring harness
	98	battery compartment
	99	arrow
	100	arrow
	101	battery
	102	needle
	103	connection
10	104	opening
	105	hearing aid component assembly

The foregoing embodiments are presented by way of example only; the scope of the present invention is to be limited only by the following claims.